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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,021	LITTLE, ROGER G	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1,3,6-13 and 18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,5,14-17 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED ACTION

Claims 1-22 are pending.

Applicant's election of group III, claims 5, 14, 17, 22, in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction between group II, claims 2, 4, 14, 15, 16, and group III is withdrawn upon further consideration.

Claims 1, 3, 6-13, 18-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

Claims 2, 4, 5, 14-17, 22 are being examined.

Claim Objections

Claim 15 is objected to because of the following informalities: "angiogenesis" is misspelled. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 5, 17 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5807818. This is a double patenting rejection.

Claim 22 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 5807818. This is a double patenting rejection.

Claims 2, 15 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5837678. This is a double patenting rejection.

Claims 4, 16 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 5837678. This is a double patenting rejection.

Applicant is advised that should claim 2 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 4 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 5 be found allowable, claim 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that:

should claim 2 be found allowable, claims 5, 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof;

should claim 5 be found allowable, claims 2, 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof;

should claim 15 be found allowable, claims 5, 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof; and,

should claim 17 be found allowable, claims 2, 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The intended uses of the claimed methods do not distinguish the claims. No

difference is seen between the amount administered to inhibit angiogenesis and the amount administered to inhibit endothelial cell proliferation.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5807818. Although the conflicting claims are not identical, they are not patentably distinct from each other because a 23-25 kD amino-terminal fragment of BPI is an approximately 21 to 25 kD amino-terminal fragment of BPI.

Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5837678. Although the conflicting claims are not identical, they are not patentably distinct from each other because a 23-25 kD amino-terminal fragment of BPI is an approximately 21 to 25 kD amino-terminal fragment of BPI.

Claims 2, 4, 5, 14-17, 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No.

5856302. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present specification defines a BPI protein product as including biologically active fragments of BPI (page 8, full paragraph 4). BPI protein fragments may be provided in the form of linear peptides (paragraph bridging pages 11-12). Such peptides may be provided in the form of dimers (paragraph bridging pages 11-12), as recited in the claim of the patent.

Claims 2, 5, 14, 15, 17, 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Nos. 5783561, 5639727, 5627153, 5578572, 5348942, 6509317, 6440936, 6376465, 6242418, 6214789, 6191112, 6162788, 6107280, 6017881, 6013629, 5990086, 5952302, 5945399, 5935930, 5888973, 5827816, 5770561, 5756464, 5753620, 5741779, 5686414, 5646114, 5578568, 5494896 directed to the administration of a BPI protein product. Although the conflicting claims are not identical, they are not patentably distinct from each other because no difference is seen between an amount of a BPI protein product effective to inhibit angiogenesis or endothelial cell proliferation and the amount administered in the claims of the patents. The intended uses of the claimed methods do not distinguish the present claims from claims of the patents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 5, 14, 15, 17, 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Weiss (u6). Weiss discloses whole animal experiments, showing protection against administered LPS by recombinant holo-BPI, as well as by recombinant NH_2-terminal fragment (page 1129, left column, full paragraph 1). The intended uses of the claimed methods do not distinguish the claims from Weiss. No difference is seen between the amount administered to inhibit angiogenesis and the amount administered to inhibit endothelial cell proliferation and the amount showing protection against administered LPS.

Claims 2, 5, 15, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Opal (v6). Opal discloses the administration of BPI and protection from lethality following endotoxin challenge thereby (page 351A, right column, second Abstract). The intended uses of the claimed methods do not distinguish the claims from Opal. No difference is seen between the amount administered to inhibit angiogenesis and the amount administered to inhibit endothelial cell proliferation and the amount showing protection from lethality following endotoxin challenge.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 5, 14, 15, 17, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Opal (v6) and Ooi (w6). Opal discloses the administration of BPI and protection from lethality following endotoxin challenge thereby (page 351A, right column, second Abstract). Opal does not teach the administration of a 25-kDa fragment of BPI.

Ooi teaches a 25-kDa fragment of BPI that possesses the bactericidal and envelope-altering activities of the 60-kDa parent protein. On a molar basis, the fragment is as potent as holo-human BPI against rough Escherichia coli, is more potent than holo-BPI against more resistant smooth E. coli, and retains the specificity of BPI toward Gram-negative bacteria. NH_2-terminal amino acid sequence analysis shows that the fragment is derived from the NH_2 terminus of the BPI molecule. These findings suggest that all of the molecular determinants of the antibacterial properties of BPI reside within the NH_2-terminal 25-kDa segment, implying a novel structural/functional organization for a cytotoxic protein. See the Abstract. Ooi does not teach the administration of BPI and protection from lethality following endotoxin challenge thereby.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer BPI and protect from lethality following endotoxin challenge thereby, as taught by Opal, and to modify that teaching by administering the NH_2-terminal 25-kDa segment of BPI, as taught by Ooi, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because on a molar basis, the fragment is as potent as holo-human BPI against rough Escherichia coli, is more potent than holo-BPI against more resistant smooth E. coli, and retains the specificity of BPI toward Gram-negative bacteria, and all of the molecular determinants of the antibacterial properties of BPI

reside within the NH_2-terminal 25-kDa segment. The intended uses of the claimed methods do not distinguish the claims from Opal and Ooi. No difference is seen between the amount administered to inhibit angiogenesis and the amount administered to inhibit endothelial cell proliferation and the amount showing protection from lethality following endotoxin challenge. The invention is prima facie obvious over the prior art.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

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FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MARCH 19, 2003